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This workshop was sponsored primarily by the National Institutes of Health (NIH) and the American Academy of Orthopaedic Surgeon. (AAOS) to discuss the emerging technoogy of digital image graphics, robotics, and computer informatics and their potential impact on orthopaedic surgery in research, education and patient care. Because of the current pressure of health care reform and drastically reduced rates of medical reimbursement in both the private and public sectors, the relative merits and costs of these technologies were carefully assessed by all speakers and discussed by the participants. The objective of this workshop was to learn about current state-of the art developments and potential applications of these emerging technologies in orthopaedics from leaders in the field through careful assessment, rational prioritization and exploration. Break-out sessions were held in a rigorous format that successfully stimulated exchange of knowledge and future collaborative opportunities for research and development among the participants. Innovative ideas and application possibilities generated from the brain-storming exercises will be disseminated throughout this report and in a web site on the internet.

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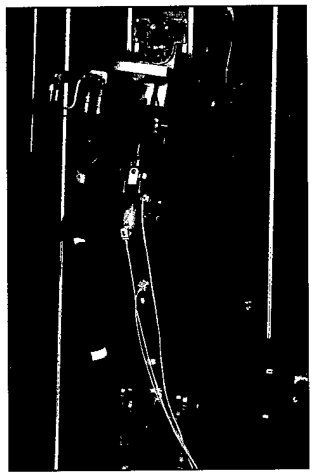

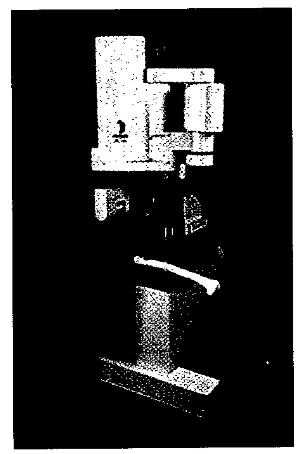

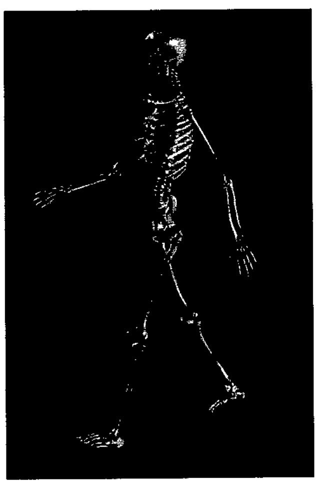

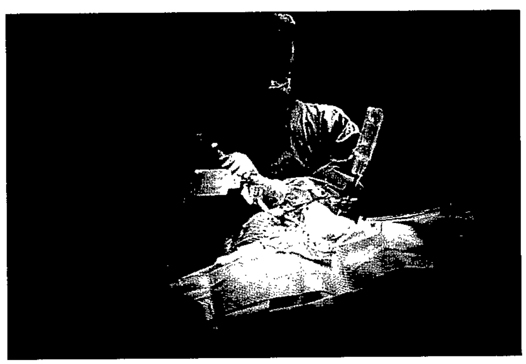

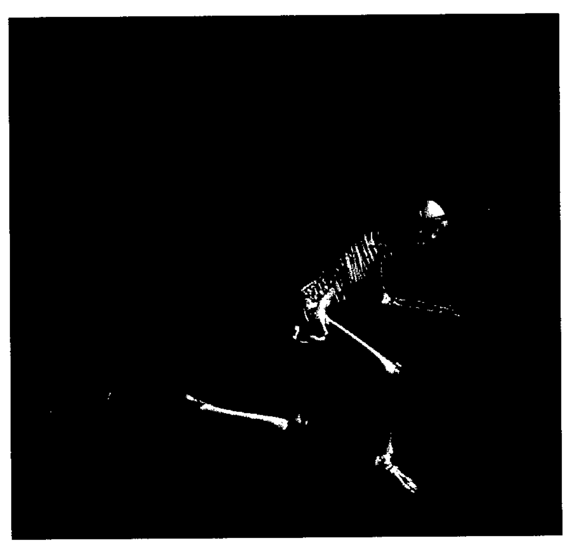

- *Simulators*
- *Image Guided Interventions*
- *Surgical Robots*
- *Virtual Biomechanical Models*
- *Pre-operative and Pre-treatment Planning*

Baltimore, Maryland
April 30 - May 3, 1998

Acknowledgments

This workshop was funded primarily by the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Center of Medical Rehabilitation Research, National Institute of Child Health and Developmental Diseases (NIH) and the American Academy of Orthopaedic Surgeons. Additional funds were also provided by the National Science Foundation, Army Medical Research and Material Command, Mitsubishi Information Technology Center and the Corporate Research and Development Division of General Electric. Many orthopaedic training programs funded their new investigators to take part in this workshop.

We are very grateful to the Chair of the Committee on Research, AAOS, Dr. Mike Erlich, who supported this workshop all the way and to Karen Schneider and Belinda Duszynski from the AAOS headquarters for taking extra time and care to make sure that it was carried out successfully. Special thanks also to Ellen Von Karajan, Nancy Barrett, and everyone in the Johns Hopkins Biomechanics Laboratory. Without their planning, organization and meticulous direction, this workshop would not have been as well organized. We would also wish to thank Sung Pak and Mari Nakamura in advance for their willingness to take on the project of transferring this report plus exciting graphics and video to a special Home Page on the Internet.

This report is respectfully submitted by:

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EXECUTIVE SUMMARY

WORKSHOP OBJECTIVE

Sponsored primarily by the National Institutes of Health (NIH) and the American Academy of Orthopaedic Surgeons (AAOS), this workshop took place in Towson, Maryland from April 30 through May 3, 1998 to discuss the emerging technology of digital image graphics, robotics, and computer informatics and their potential impact on orthopaedic surgery in research, education and patient care. The workshop was attended by a total of 78 participants including young orthopaedic surgeons and scientists and those with strong interest/expertise in related technologies in other medical disciplines both from the USA and abroad. Because of the current pressure of health care reform and drastically reduced rates of medical reimbursement in both the private and public sectors, the relative merits and costs of these technologies were carefully assessed by all speakers and discussed by the participants. Discussions about the cost-effectiveness issue continued during the break-out sessions throughout the workshop.

The objective of this workshop was to learn about current state-of-the-art developments and potential applications of these emerging technologies in orthopaedics from leaders in the field through careful assessment, rational prioritization and exploration. Break-out sessions were held in a rigorous format that successfully stimulated exchange of knowledge and future collaborative opportunities for research and development among the participants. Innovative ideas and application possibilities generated from the brain-storming exercises will be disseminated throughout this report and in a web site on the Internet.

BACKGROUND AND RATIONALE

Orthopaedics has set the standard for basic research and the clinical dissemination of scientific knowledge for the past two decades and we expect this to continue with the new engineering technology as well. Yet there is still much to do to meet the challenge of directing these exciting new technologies for proper, effective and justified utilization in orthopaedic patient care, for the training of health care personnel, and for guiding biomedical research in the next century.

Influenced by unprecedented advances in engineering technology, medicine and surgery have gone through two distinct periods of evolution as they moved from the Industrial Age early in the 20th century to the Information and Communication era at the present time. The new discipline of bioengineering was the catalyst that fostered the transition from one period to another, putting new technology and science on firm and rational ground in the medical arena.

As we march into the next century carrying with us newly acquired knowledge, instruments, techniques, as well as very challenging problems, we stand at the threshold of the most exciting bioengineering evolution in medicine and surgery with a significance and impact matching that of other medical sciences. Such enthusiasm will not be dampened by health care reform and shrinking medical research dollars. On the contrary, the new engineering technology should produce the necessary tools and methodology required for permitting all basic science research results to be effectively disseminated into practical, reliable and affordable clinical applications.

Biomechanical engineers and orthopaedic surgeons have been quantifying muscle and joint forces and bone stresses under both static and dynamic conditions for years, but rarely have the analyses been performed in parallel nor have the results been displayed on realistic models depicting the system responses under physiological function. Virtual reality models combined with medical robotics, computer-assisted surgery and pre-operative planning can elevate this branch of bioengineering to a new level of excellence with exciting and relevant clinical applications. With the help of these unique but previously unavailable capabilities, we are able to achieve the goal of "Visualization of Biomedical Computation" in the field of biomechanics which will put orthopaedic surgery on an even stronger and more rational foundation.

SPECIFIC ENGINEERING TECHNOLOGIES ASSESSED

To assure that emerging technologies will play a role in future orthopaedic practice and education we focused on four areas which we believe have the greatest potential for significant enhancement of patient care quality. Our discussions evaluated their proper scope and addressed relevant areas of application. These four areas are:

Anatomical/Physiological/Surgical/Mechanical Simulators
Image-Guided Procedures (for both local and remote site applications)
Surgical Robots and Navigators (for computer-assisted surgery and therapies)

EXECUTIVE SUMMARY

OUTCOME OF DISCUSSIONS

In reference to each of the technology areas, we accomplished the following specific aims:

Reviewed recent engineering technology transfer to medicine and surgery
Ascertained the potential merit of these technologies in orthopaedics
Defined a rationale for federal and private funding for such non-traditional medical science/ technology
Attracted new investigators with diverse backgrounds to form collaborative teams and multi-institutional programs

Definitions related to each of these areas and their enabling technologies were refined. Technical and non-technical issues that might affect their future utilization were debated and summarized based on consensus. Critical needs and future development and research priorities were summarized as key recommendations for each of the technical areas.

In addition to the publication of this Workshop Report, an Action Group has been formed among the participants to assure follow-up actions in various Institutes of NIH, NSF, Army-MRMC and other relevant government agencies, private foundations, professional societies and medical industries. Future workshops on specific topics to promote further collaboration in each area are also expected to result. All in all, this workshop has fulfilled its preset goals.

OVERALL RECOMMENDATIONS

1. **NIH should sponsor a conference on New Engineering Technology Transfer in Medicine and Surgery to define the common needs in each medical subspecialty so that a Consensus Document and an ad-hoc working group concerning these technologies can be established to work on future RFAs shared by all Institutes and Centers within NIH.**

2. **AAOS should appoint a stand-alone ad-hoc committee on New Engineering Technology Transfer to encourage, nourish and coordinate the related activities.**

3. **Funds will be solicited by the Action Group to maintain and up-date the Home Page on the Internet.**

4. **Workshops on each of these four technology areas should be organized and co-sponsored by ORS, AAOS and OREF with shared funding from different orthopaedic professional societies to continue refining the scope and needs of these technologies in orthopaedic surgery.**

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ANATOMICAL/SURGICAL/MECHANICAL SIMULATORS

SIMULATOR 1: ARTHROSCOPIC SIMULATOR

OBJECTIVES

Development of an arthroscopic simulator for orthopaedic surgeons is analogous to the airlines' use of flight simulators for pilot training. Routine take-offs and landings can be practiced again and again for specific aircraft as can various emergencies and rough weather conditions. Simulation-based flight training avoids the expense of pulling a commercial aircraft off line as well as eliminating potential risks to passengers. Because arthroscopic surgery of the knee is one of the most common orthopaedic procedures in the United States with over two million operations performed each year, ranging from simple diagnostic procedures to reconstructions on the anterior cruciate ligament, this work group chose to focus on an arthroscopic simulator for the knee.

The work group identified four areas that should be defined prior to proceeding with development of the arthroscopic simulator: target users and user groups, technical requirements, evaluation criteria and sources of funding:

DEFINE TARGET USES AND USER GROUPS

Selection of the users defines the functions which the simulator could fulfill. Note that the following suggestions are by no means an endorsement of the use of the simulator in any given scenario, only a hypotheses of its potential functions. Orthopaedic training programs could use the device as a screening tool for potential applicants or at least to measure their capabilities as they enter the program. Later in the program, the simulator could be used to acquaint PGY I, II and III residents with the basics of arthroscopic surgery. At the end of training, the simulator could be used again as an evaluation tool for PGY IV, V and fellows.

It should be noted here that the American Board of Orthopaedic Surgery (ABOS) is considering the use of an arthroscopic simulator as a component of the certification process. Practicing orthopaedic surgeons would most likely use the simulator for continuing medical education, either in refresher courses covering previously learned techniques or as an adjunct to introducing new arthroscopic surgical techniques. The ABOS could also consider using the simulator for the recertification of surgeons and the Arthroscopy Association of North America (AANA) could use the same simulator as part of the test of a certificate of added qualification. It is also quite conceivable that patient-specific data from MRI and other sources could be used to create rehearsal scenarios for particularly challenging cases.

Discussions with representatives from the Office of Device Evaluation of the FDA suggest that their approval would be necessary if the simulator were to be used as a clinical tool in that manner. The last group is the orthopaedic industry. Companies specializing in arthroscopic equipment and accessories could use the device for product development, surgeon training and possibly as a sales tool.

DEFINE TECHNICAL REQUIREMENTS

The technical requirements for the arthroscopic simulator are based upon the level of simulation demanded from the system and the content development process. Limiting the level of simulation would lead to simpler computer and interface requirements, making it easier to create a marketable device. This would, however, provide a device of limited capacity. Basic simulator tasks would include portal selection, triangulation of the scope and probe, avoidance of cartilage surfaces and visualization of anatomic structures. Intermediate tasks would include simple menisectomy or synovectomy, while anterior cruciate ligament reconstruction, cartilage transplantation and meniscal repair would be considered advanced tasks. With increasing levels of task difficulty, the interface development and programming of the synthetic environment would also become more challenging. The most realistic simulator would allow the surgeon to practice upon the simulator with data derived from MRI scans of a particular patient. While this scenario promises the greatest variety of pathology, it also requires FDA approval if the simulation is a rehearsal for a particular case.

DEFINE EVALUATION CRITERIA

If the arthroscopic simulator is to become a useful teaching and evaluation tool, we will have to establish "construct validity" – the ability to distinguish between novices and experts who use the same machine. Initial data gathered from beta testing sites could be used to establish standards for a particular simulation program running on a given simulator. Initially, we expect that the minimum level of competence will be the easiest to establish,

continued

whereas it will require an extended period of beta-testing to establish an advanced skill level. Evaluation criteria utilized in judging performance on the simulator would include, but not necessarily be limited to time-based tasks, procedure-based evaluations, accuracy in task, identification of structures and pathologies, and simple proprioception.

DEFINE SOURCES OF FUNDING

The work group polled leading experts at the NIH/AAOS workshop and received estimates of between $750,000 and $1.5 million to develop the initial simulator including appropriate software and haptic interfaces. These costs would easily outstrip the resources of the leading orthopaedic specialty organizations but could be within the range of a SBIR grant from NIH. Additionally, the military has been very active in telepresence surgery through DARPA and may be willing to fund a portion of the project as a tool for training its orthopaedic residents and possibly providing remote telementoring of arthroscopic procedures at distant bases.

BACKGROUND AND RATIONALE

Visualization of the operative field through the arthroscope is strongly influenced by surgical experience, technique and the close proximity of anatomic structures to the instrumentation. Unlike other orthopaedic procedures, such as tendon repair and basic fracture fixation, there is little, if any, crossover in technique from other procedures and there are no readily available training models. Thus, successful and timely completion of an arthroscopic procedure about the knee is almost entirely dependent upon the surgeon's experience with earlier clinical procedures involving real patients in a real operating room.

Training in arthroscopic surgery for the approximately 3500 orthopaedic residents routinely begins in the operating room utilizing an apprenticeship technique: the resident observes faculty or senior residents perform the procedure and then he or she gradually increases his or her level of involvement with each succeeding case. However, this mode of teaching is inherently slow in the initial stages which increases overall time and operative expense. In today's managed care environment, this additional operative time is less likely to be tolerated by insurance payers and could eventually lead to a shift of necessary surgical cases away from teaching centers. Learning arthroscopy by apprenticeship is inherently inefficient, even for the most accomplished resident, because clinical cases encompass a broad range of activities that are not directly related to learning how to manipulate arthroscopic instruments.

Board certified orthopaedic surgeons who wish to enhance their arthroscopic technique, or learn new arthroscopic procedures, have the option of attending instructional courses put on by various orthopaedic societies such as AAOS and AANA. These courses typically utilize fresh cadaveric specimens which are both expensive and difficult to obtain. There is no guaranteed uniformity among these specimens, however, and it is difficult to reproduce realistic and consistent pathologies in these knees. It is estimated that at least half of the AAOS's 17,000 members routinely perform arthroscopic procedures about the knee and that several thousand consider arthroscopy to be a major focus of their practice.

Just as pilots must acquire various skills to fly an airliner safely and efficiently, so too must the orthopaedic surgeon. Spatial awareness of the hidden interior of the knee is essential in properly manipulating arthroscopic instruments about the joint without damaging the cartilage surface. First hand knowledge of normal and pathologic anatomy is required to remain oriented to the tunnel-view of the arthroscope as is the ability to triangulate the instruments through proprioception alone when the view is obscured.

CURRENT TECHNOLOGY AVAILABLE

The American Board of Orthopaedic Surgery (ABOS) recently sent out a request for proposals to develop an arthroscopic simulator and received replies from Boston Dynamics, Inc. (BDI), Anatomic Visualization, Inc. (AVI) and Musculographics. AVI recently received a grant from the Orthopaedic Research and Education Foundation (OREF) to develop a prototype arthroscopic simulator. Other groups working upon arthroscopic simulators but not submitting RFPs included the Mitsubishi Electric Research Lab (MERL) and Prosolvia. MERL is building a prototype system for simulation and training in arthroscopic knee surgery in a collaborative project between MERL, Brigham and Women's Hospital, Carnegie Mellon University and the Massachusetts Institutes of Technology. Prosolvia is a Swedish company developing a shoulder arthroscopy system.

continued

ANATOMICAL/SURGICAL/MECHANICAL SIMULATORS

Current Technology Available, continued

The ABOS selected BDI to develop a prototype system which was demonstrated in April, 1998, at the AAOS headquarters in Rosemont, Illinois. The system ran on an SGI Onyx and utilized one SensAble Phantom to hold the arthroscope and provide haptic feedback. The synthetic environment consisted of a volumetric model from ViewPoint Data Labs with texture-mapped pathologies. No soft tissues other than the medial and lateral menisci and the anterior cruciate ligament were demonstrated in this proof-of-concept model. The developers note that soft tissue layers and an additional portal could easily be added to the simulator.

POTENTIAL ORTHOPAEDIC APPLICATIONS

The arthroscopic simulator brings several advantages to orthopaedic training. Uniform training scenarios could be made available to all residency programs, providing a consistent standard although the software could be adapted to local, regional and national needs. A stand-alone simulator would also remove time constraints from resident training, obviating the need for patient and clinical equipment availability. There would be no risk to patients while trainees took as much time as necessary to understand the pathology of the case and develop their physical and cognitive skills. These various pathologies would then be available to the entire network of simulators through the exchange of program disks or even the Internet.

The ability to record and access the performance of trainees also lends itself to recording "expert" performances from practitioners and playing those back in training sessions as well as archiving them for future reference. Trainees could then attempt to emulate these experts as they improve their surgical skills. In addition to the cost and time savings from avoiding expensive training sessions in the operating room, there would also be a substantial savings in the use of costly disposables, such as shavers and abraders, since these tools would simply be modeled within the synthetic environment. Moreover, new tools and instruments could be tested in the synthetic environment prior to final development, thereby making the simulator attractive to the orthopaedic industry.

Finally, the arthroscopic simulator offers the potential to evaluate prospective orthopaedic trainees in a clinically relevant environment. Studies would have to be conducted to compare first year simulator scores with fifth year scores to determine if there were any predictive value of simulator screening.

TECHNICAL NEEDS AND RELATED ISSUES

The development of the arthroscopic knee simulator must take into account the availability of the components for a hardware construct, the design of the synthetic environment and the anticipated uses for the device. The hardware construct encompasses three major components: the computer platform, the video display and the haptic interface. The computer platform must be able to handle the millions of calculations necessary to provide real-time visualization with little or no latency in response to the user's input. This typically requires a graphics workstation such as the Onyx from Silicon Graphics although it is anticipated that other less expensive, high-end systems could handle simpler constructs. The video display for either system can be as simple as a 19 inch computer monitor or include three dimensional representations utilizing liquid crystal shutter glasses (CrystalEyes) and the appropriate signal mix of a standard monitor.

Replicating the feel of the arthroscopic instruments interacting with soft tissue, cartilage and bone is the most challenging aspect of developing a useful arthroscopic simulator. This ability to recreate the forces and torques experienced in actual activity is known as haptic feedback. By monitoring the position of the arthroscope with respect to a mathematical model of the knee and it surrounding tissues (the "synthetic environment"), the system can both recreate the appropriate view for the video display as well as the proper forces to be exerted back upon the surgeon's instruments. This involves a collision detection algorithm which prevents the instruments from moving through "solid" surfaces. The arthroscopic instruments are mounted on two haptic feedback devices known as "Phantoms" from SensAble Technologies of Cambridge, Massachusetts. The Phantom monitors the position of the instruments and provides force feedback to the user. The forces that the user would normally apply to the lower limb during arthroscopy are directed through a surrogate leg that is instrumented to measure flexion/extension and varus/valgus, angulation.

The mathematical representation of the physical world, in this case a human knee, is known as the synthetic environment. The synthetic environment replicates the visual, mechanical and behavioral aspects of the knee

continued

through a combination of control, modeling and content software. The control software moderates the haptic interface and interacts with the modeling software to indicate when the user has collided with a surface. The modeling software is based upon three-dimensional models of the knee and interacts with the content software to send the appropriate images to the video display. The content software is responsible for the actual appearance of the knee on the display and includes knee pathology such as meniscal tears and chondral defects as well as normal anatomy. Content software also monitors task-specific performance such as shaving a torn meniscus or capturing an intra-articular loose body.

Finally, it is important to note that with multiple groups already working on developing an arthroscopic simulator, there is a very good chance that they will build simulators with varying levels of simulation. Cheaper, low end simulators might be used for teaching basic skills with the top of the line machines relegated to learning/evaluation centers.

NON-TECHNICAL ISSUES

Development of the arthroscopic knee simulator encompasses several areas shared by all new technologies. Licensing of the production of the arthroscopic simulator will be a complicated issue. Much of the hardware is off the shelf as are some of the basic computer algorithms, but the intra-articular pathology and the surgical techniques are unique to orthopaedic surgery. How do we divide the ownership of intellectual properties between hardware developers and content providers when much of the input may come from Academy members working pro-bono to provide a realistic synthetic environment?

Control of access to arthroscopic simulators may become a sensitive issue as other specialty societies such as rheumatologists and podiatrists push for the capability to perform arthroscopic surgery. This could be controlled in part by regulating the standards of evaluation used on specific simulators, but then the consortium that develops the simulator will have to establish guidelines for its use.

In addition to content development, it will be just as important to evaluate whether training on a given simulator is cost effective, known as "training transfer" in the aircraft simulator industry. Given any level of simulator, do the trainees and their supervising agency save enough time and money to justify the cost of development?

Finally, what are the liability issues involved in developing a medical simulator? Can the developers be held accountable if a surgeon is involved in an arthroscopically related malpractice suit after the surgeon has completed training on an approved simulator? Some of these questions could be answered by polling the developers of laparascopic simulators.

Once the basic technology of the simulator has been developed and it becomes a fixture in orthopaedic training and evaluation, it is inevitable that there will be technological spin-offs, just as there were for laparascopic simulators. Projects already underway allow a surgeon to monitor (telementoring) a laparascopy performed by another surgeon over the Internet as well as interact with the surgery through a robotic assistant (remote telepresence surgery). The simulator development group should keep these potential spin-offs in mind when developing standards and administrative controls for the arthroscopic simulator.

RECOMMENDATIONS

The recommendation of the simulator work group is that a national work group be established through a joint venture between NIH and AAOS. This national work group should also include various specialty societies and certifying organizations, such as the Arthroscopy Association of North America (AANA) and the American Board of Orthopaedic Surgery (ABOS) in order to assure broad applicability of standards. It should also provide a contact point for all arthroscopic simulator developers to coordinate on-going activities, screen developing technologies and avoid unnecessary duplication of effort and technology. Additionally, it should maintain contact with the FDA and advise them if the simulator is ever used for individual case rehearsal for a specific patient, robotic enhanced surgery, telementoring or remote telepresence surgery.

This work group should also explore relationships with the orthopaedic industry to establish the needs of arthroscope and arthroscopic instrument manufacturers, and work with the training industry to help determine standards of evaluation. Finally, it should continue to identify all available technology sources.

continued

ANATOMICAL/SURGICAL/MECHANICAL SIMULATORS

Recommendations, continued

The Federal Aviation Administration (FAA) may also serve as a source of information regarding the development of sophisticated simulators since they regulate some of the most advanced devices in the world. The FAA has experience in administering and enforcing standards as well as maintaining them over an extended period of time.

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SIMULATOR 2: BASIC SKILLS SIMULATOR

OBJECTIVES

We hypothesize that a basic surgical skills simulator will allow rapid and reproducible acquisition of skills and will enhance our ability to instruct on complex issues of patient selection, intra-operative judgment, handling of complications and complicated reconstructive tasks.

BACKGROUND AND RATIONALE

Complex surgical procedures can be broken down into successful completion of a number of basic surgical tasks. Orthopaedic residency involves a prolonged and at times poorly focused and poorly supervised instruction in surgical tasks, which is not evenly distributed or evaluated among trainees.

DEFINITIONS AND TERMINOLOGY

Basic surgical skills: component parts of complex surgical reconstructions.
Validation: demonstration of efficacy in simulation of actual surgical tasks.

CURRENT TECHNOLOGY AVAILABLE

Multiple basic simulators

1) Delp - Ballistics
2) BDI - Arthroscopy, colon repair
3) Haptic force feedback device
   Eagle Simulation, Inc. Mannequin for resuscitation is very sophisticated and very expensive 500G), though no haptic input is currently available

Validation Needs

1) Construct validity - assumed to be present
2) Instructional effectiveness - need a Gold Standard
   A) Microsurgical animal patency
   B) Animal model
   C) Cadaveric model
   D) Controlled human trials
      Predict that instructional effectiveness may be inversely proportional to the training (efficiency of simulator)
3) Transfer
   A) At best can be estimated
   B) Percentage efficiency of simulator will be inversely proportionate to frequency of occurrence, e.g., how often will an airplane engine shut down in actual in flight training? This rare situation can be easily and repeatedly taught to near perfection on simulator.

continued

4) Assessment Variables
    - A) Time to completion of task
    - B) Deterioration of skills/time
    - C) Repeatability of task
    - D) Fatigue
    - E) Diurnal variation
    - F) Relationship of success to on-call schedule, workload, etc.

RECOMMENDATIONS

Develop multi-functional task surgical skills simulators for:

1) Hard Tissue
    - A) Bone Shaping (drill, k wire, saw, broach, AO fixation)
    - B) Bone Manipulation (closed reduction, open reduction, dislocations, casting techniques)
    - C) 2D/3D Conversion Algorithms (fluoroscopy, osteotomies, malalignment)
2) Soft Tissue
    - A) Dissection (3D forearm, scalpel penetration, tissue planes)
    - B) Tissue Repair
        1. Knot tying (tension, slippage, breakage)
        2. Microscopy (nerve, vessel)
        3. Tendon
        4. Ligament
    - C) Wound Closure/Debridement
        1. Flaps
        2. Z-plasty
        3. Infection

Participants

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SIMULATORS 3: DEVELOPMENT OF FUNCTIONAL AND ANATOMICAL MODELS

OBJECTIVES

- Develop and improve models of the neuromusculoskeletal system and their validity for simulating function, pathomechanics and neural control. These models may be comprehensive or pathology specific and include but not be limited to: osseous geometry, soft tissue material properties, muscle dynamics, skeletal dynamics and neural control. These models should be capable of including variation of age, gender, culture and pathophysiology.

- Validate these models using experimentally obtained data. In some cases, appropriate sensors will need to be developed.

- Utilize these models to improve our knowledge of how the structure, control, and neuromusculoskeletal dynamics contribute to the pathomechanics of patients with impairments, functional limitations or disabilities.

- Utilize these models to develop techniques to definitively identify the underlying cause and long term consequences of a specific abnormality.

- Assess the efficacy of existing treatment methods and development of new treatment methods based on these conceptual models utilizing pre- and post-treatment objective measures of impair ment and functional limitations.

BACKGROUND AND RATIONALE

The vast majority of individuals with neuromusculoskeletal pathologies present clinically with pain, aberrant activities of daily living (ADL), posture and/or locomotion. The role of structure and function which contributes to pathomechanics needs to be evaluated. The difficulties in establishing a cause and effect link between abnormalities, aberrant structure, and pathology stem from deficiencies in the knowledge of the mechanics and neural control of normal and pathological function. Neuromusculoskeletal models can provide a theoretical framework from which to study this relationship for a given pathology.

This knowledge and objective data will enhance the assessment, treatment planning and prognostic capabilities of clinicians who manage patients with impairments, functional limitations and disabilities. Non-invasive sensors of human movement, neural signals, muscle and ligament forces and bone stresses are also needed. Means to extract such data from deep structures are not know today; however, opportunities to innovate such sensors may be offered by X-ray, CT, MRI, PET, ultrasound, radioactive tracers and microtransducers or magnetic or specific-chemicals-sensitive particles parentrally injected into the vascular system.

RECOMMENDATIONS

It is recommended that agencies develop funding mechanisms to support research to meet the above objectives.

Participants

Branislav Jaramaz, Ph.D.	Shadyside Medical Center	Moderator
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IMAGE GUIDED PROCEDURES

OBJECTIVES
Image guided procedures (IGPs) provide an opportunity to save significant costs by decreasing operating room time, length of hospital stay and use of other hospital resources. They should be minimally invasive, and should enable both the experienced and the new surgeon to perform a wide range of procedures better, in terms of both improving outcomes (using AAOS standards for outcome measures) and reducing complications. Additionally, they should be applicable to a large patient population.

BACKGROUND AND RATIONALE
Optimally, the incorporation of contemporary imaging modalities and computers should minimize the invasiveness of orthopaedic procedures, extend the capabilities of current surgical applications, function as a clinical research tool and save costs.

Although portable fluoroscopy has been the mainstay of orthopaedic surgeons and is well accepted, there has been some resistance to incorporating IGPs into their practices. Objections have included a steep learning curve and fears that IGPs could give unskilled surgeons a license to perform poor surgeries. If these new procedures are to be accepted, it must first be demonstrated to surgeons that they are more accurate, cost effective and safer than other currently available methods.

DEFINITIONS AND TERMINOLOGY
Image Generation: Pre-operative image acquisition through current modalities: CT, MRI, Ultrasound, fluoroscope, etc. Segmentation and other image processing. Surface or volume rendering.

Registration: The alignment of the virtual model with patient space, classically done in the surgeon's mind, could be more automated and reliable.

Tracking: Objects (bones, ligament, tendons, etc.) and surgical tools during surgical procedures.

Surgical planning: Optimization of orthopaedic procedures using patient data.

Navigation: Execution of surgical plan.

CURRENT TECHNOLOGY AVAILABLE
Clinical applications currently being developed include pedicle screw placement (since 1993); posterior spinal instrumentation; total joint replacement; pelvic fracture fixation; osteotomy; and ACL/PCL reconstruction.

POTENTIAL ORTHOPAEDIC APPLICATIONS
Potential applications that could have an immediate impact in orthopaedic procedures include: iliosacral screws, pelvic fractures and trauma cases (fractures of the femur, tibia and humerus, including interlocking screws); total joint replacement (hip and knee); anterior spinal surgery (in terms of less invasive procedures); and intervertebral body fusion/release.

Areas deserving further research include: pelvic osteotomy; growth plate arrest; tumor biopsy/excision; osteotomy (femur and tibia); vertebroplasty; and indirect reduction (fractures).

For all of the above applications, the following imaging steps are required:

- Image acquisition and processing (2D and 3D).
- Pre-operative planning including functional predictions that could be done right in the operating room.
- Registration.
- Orientation (navigation): Could also include updating the registration during surgery.
- Validation of both technical and clinical outcomes in terms of both system and surgical accuracy.

continued

IMAGE GUIDED PROCEDURES

TECHNICAL NEEDS/ISSUES

Short term

- Fully automated segmentation algorithms for generation of models that emphasize speed and accuracy. These would provide a significant decrease in processing time by eliminating human involvement.
- Improvement of independent tracking of multiple objects for manipulation in the virtual model.
- Accurate calibration of multiple imaging modalities (image fusion) for a hybridized reality.
- Reliable real time assessment of registration landmarks and continuous tracking (dynamic reference) that provide more flexibility in the operating room. This would allow for validation of the accuracy of currently existing and new tracking systems that include optical, sonar, magnetic, lasers and radio frequency.
- Standardized validation of accuracy, registration and surgical planning execution to minimize variability in procedures.

Longer term

- More accurate virtual models that combine rigid and deformable objects to mimic the responses of the hard and soft tissue in orthopaedic procedures.
- Standardized multi-modular computer components that would allow:
  - Additions of new procedures and educational resources.
  - An updated outcome library (including pre-operative parameters and patient data) that could be accessed via the Internet for future use in pre-operative planning and education purposes.
  - Multi-platformed software which could be used on different computer systems.
  - Utilization of similar procedures in different surgical disciplines for reduction of operating costs and software development time.
  - Accurate data compression algorithms for efficient storage of the tremendous amounts of image and surgical data.
  - Education program development: pre-operative planning, interactive anatomy, surgical simulation.
  - Real time adjustments to the optimized pre-operative surgical plan in the operating room to account for deviations in complicated procedures.

RECOMMENDATIONS

The group recommends a follow-up meeting in two years to evaluate progress made in the acceptance of new technologies and procedures in the general, medical and industrial communities. This meeting would also be used review the effectiveness of generating fiscal support for image guide systems development. A further discussion of orthopaedics as an ideal environment for the development of image guided systems, due to the high quality imaging characteristics (bones) and lack of the common pitfalls normal associated with other medical disciplines (i.e. unreliable registration), is also recommended.

Participants

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SURGICAL ROBOTS

OBJECTIVES

The field of medical robotics offers a number of attractive features. It has potential to provide better quality patient care by improving current procedures, allowing additional capabilities that are currently unavailable, and improving the means of evaluating the success of surgeries. The specific objectives of this technology include:

- Improve accuracy of procedure.
- Allow finer control.
- Increase reproducibility (consistency).
- Incorporate complicated, detailed and voluminous image data in surgical execution.
- Allow remote activation which could expand access to operator expertise for patients.
- Allow longer endurance than humans in the same task.
- Improve safety - a robot can safely intervene in situations where infection risk to a human operator may be high.
- Minimize invasion of procedure.
- Provide new possibilities for miniaturization of the surgical task.

DEFINITIONS AND TERMINOLOGY

Robot: A re-programmable, multi-functional manipulator designed to move material, parts, tools, or specialized devices through various programmable motions for the performance of a variety of tasks - (Source: ROBOTIC INSTITUTES OF AMERICA, 1979). For the field of medical robotics, we wish to broaden and modify this definition. We classify medical robots in two ways:

Functional classification

- Dexterity enhancement. These robots are directly controlled by some input device used by the sur geon - e.g., to reduce tremor during microsurgery, etc. The patient may be geographically remote from the surgeon.
- Precision localization. These allow precise location of predetermined surgical locations (e.g., based on a pre-operative image study.)
- Precision manipulation. These robots operate on the patient in some fashion based on a presurgical plan, rather than directly by the surgeon's control.

Technological classification

- Autonomous. The control of the manipulator is based purely on a pre-operative or intra-operative plan.
- Supervisory. The system provides a means of guiding the surgeon to accurately perform the operation.
- Teleoperated. The robot is controlled directly by input devices used by the surgeon at a different location during the operation.

Computer assisted surgery: The group discussed the more general term of "computer assisted surgery" which encompasses medical robotics as well as pre-operative planning systems and image-guided systems. Positioning and orienting via computer input, trajectory planning and assisted preparation (drilling/cutting/sawing) were defined as the key elements of these systems specific to medical robotics.

CURRENT TECHNOLOGY AVAILABLE

A small number of medical robots in all of the above categories have already been applied in actual orthopaedic cases. More broadly, other surgical robots have found clinical application in the fields of neurosurgery and prostate surgery. In addition to these robots which have reached the stage of clinical trial, many more prototype systems have been developed in research laboratories.

POTENTIAL ORTHOPAEDIC APPLICATIONS

- Total hip replacement - more consistent, precise placement of cup and stem.
- Total knee replacement- more consistent, precise placement of femoral, tibial, patellar components.
- Spine - accurate placement of pedicle screws.
- Osteotomy surgery - precise cutting for realignment procedures.
- Interlocking I.M. nails
- Hip nail placement.

continued

SURGICAL ROBOTS

Potential Orthopaedic Applications, continued

- Custom implant design/fabrication/implantation.
- Minimal exposure/invasiveness techniques.
- Allograft contouring.
- Limb salvage.
- Essentially all aspects of orthopaedic surgery find potential application of such technology to improve accuracy and consistency of surgical intervention; for example:
    1. Tendon transfer planning and placement.
    2. Ligament reconstruction.
    3. Fine detail and cartilage resurfacing.
    4. Hand and other micro surgery.
    5. Total shoulder replacement.

TECHNICAL NEEDS AND RELATED ISSUES

- Accuracy, fidelity of image data (MRI/CT/PET/Ultrasound).
- Efficient, accurate registration of multi-modality (MRI/CT/PET/Ultrasound) image data, pre- or intra-operatively with the eventual ability to track internal tissue in real-time.
- Fail-safe features of mechanical design.
- Compatibility between different elements of the surgical system: imaging/computing/manipulating.
- Computing power availability vs. cost.
- Component sterilization.
- Tracking of tools, etc. Optical systems require line of sight. Magnetic systems have more accuracy problems.
- Improvement of robotic control theories.
- Expansion of feedback modalities - e.g., sound, touch.
- Other end effector options - laser, ultrasound, and emerging technologies.
- Error detection sensitivity/specificity. Error detection should be sensitive while allowing quick localization and resolution.
- MEMS: Microelectric mechanical systems. These devices are being heavily researched and promise to allow manipulation of tissues on a very small scale.
- Question: *Will the development of more precise surgical execution methods allow more scope in the design of implant components?*

NON-TECHNICAL ISSUES

- Funding. Funding problems exist in all phases needed to bring a product into clinical practice and become financially viable:
    - Development
    - Refinement
    - Technology transfer
    - Outcome study - experimental procedures are not reimbursed by health insurance
    - Waiting for regulatory (FDA, etc.) approval
    - Launching a commercial product - production, documentation, packaging, support.
- Liability issues. Any sub-optimal patient outcome may be argued to be due to the technique, whether or not the claim is valid.
- Patient and surgeon acceptance. Some skepticism and resistance on the part of both the patients and the surgeons have been encountered with trial systems.
- Licensure and intellectual property issues. Patenting of certain components of technology can impede development of systems.
- Standardization and compatibility issues.
- Lack of development of valid practical term outcome measures. Since differences in outcome may not be seen for decades, it is desirable to identify shorter term predictors of eventual outcome. Without these, it can be very hard to make a case for an innovative technique's superiority compared with conventional methods.

continued

RECOMMENDATIONS

- Medical robotics technology should be promoted to orthopaedists as a tool to provide consistent optimal performance of surgeries. Indeed, we advocate this to be the mission of these systems. While advances in implant design and surgical technique continue to improve outcome statistics, it must be remembered that for the percentage of cases where human inconsistencies do lead to sub-optimal results, the consequences are great.
- Specific efforts to increase education of the general public (including politicians, hospital administrators, insurance companies, medical and engineering academics) on the potential benefits of medical robotics should be initiated:
  - Continue to sponsor multi-disciplinary workshops on robotics and computer assisted surgery and associated subtopics.
  - Develop a centralized computer website to allow easy access to documentation of advances in medical robotics, etc.
- The increased allotment of funds for technology transfer sponsorship and development/evaluation of more powerful/shorter term outcomes research methods is strongly recommended.
- The development of a specific FDA panel for the evaluation of medical robotics/CAS technology is also proposed.
- We recommend increased funding for the advanced scientific resolution of issues in:
  - Image registration
  - Automated segmentation of images
  - Multi-modality data fusion
  - Precision control theory
  - Improved actuator technology
  - Development of innovative end effectors

Participants

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PRE-OPERATIVE PLANNING

OBJECTIVES

For each case, the needed pre-operative information depends upon the complexity of the case and the experience of the surgeon. Computer-based pre-operative planning can be considered a method to simplify complicated cases, provide information which compensates for lack of experience and verify the judgments of experienced surgeons for routine cases. The objective of computer-based pre-operative planning is to provide information which enables cost-effective improvements in existing orthopaedic procedures. The information can be related to surgical approach, treatments methods and selection of prosthetic devices. The applications developed for pre-operative planning should be made available and understandable for all orthopaedic surgeons rather than being focused on the academic surgeon with engineering support.

BACKGROUND AND RATIONALE

Computer-based pre-operative planning has been slow to develop within the orthopaedic community. Because of problems with accessibility and ease-of-use, the systems currently available for pre-operative planning are not typically utilized by orthopaedic surgeons. At this point in time, the benefits to the surgeon, in terms of improved patient outcomes and increased efficiency in the operating room, do not outweigh the costs, in terms of the added time to learn and utilize the systems, in the eyes of the majority of surgeons. Computer-based pre-operative planning has the potential to improve the ratio of patient outcomes to patient care costs, however, by providing surgeons with information about individual patients which is currently unavailable.

DEFINITIONS AND TERMINOLOGY

Pre-operative planning is the integration of data from medical images, physical exams, dynamic motion analysis, computer simulations, implant geometry, and from patient history and goals to provide one or more surgical options for an individual patient. This differentiates it from simulation which can typically be done with a generic model.

Pre-operative planning overlaps several of the other topics which were covered in the workshop, specifically simulators and image guided procedures. For example, a part of pre-operative planning is related to teaching procedures on generic musculoskeletal models which is generally related to surgical simulation. Relating the pre-operative plan to the procedure within the operating room is a part of image-guided surgery. The definitive aspect of pre-operative planning is utilizing patient-specific data to plan orthopaedic procedures based on objective data.

CURRENT TECHNOLOGY AVAILABLE

Pre-operative planning depends primarily on acquiring patient specific image data, manipulating the data and/or adding components to simulate surgical procedures and performing biomechanical analyses to assess the outcome of the procedure. Current technology available for image acquisition includes plane x-rays, CT, MRI, bone scans, stress films and DEXA. Manipulating and/or adding components to the image data is currently done utilizing plastic templates, cutting and pasting images from plane x-rays along with some software available for interactive manipulation of image data. Input data for biomechanical analyses can be obtained from a patient's history and physical exam, EMG, gait analysis, range of motion analysis, estimation of mechanical properties of the soft and hard tissues, databases describing the geometric and mechanical properties of orthopaedic components and a patient's physical goals. Current tools for biomechanical analysis include statics/dynamics analysis, musculoskeletal modeling software, finite element analysis and rigid body spring modeling (discrete element analysis).

POTENTIAL ORTHOPAEDIC APPLICATION

Pre-operative planning could be used for virtually all orthopaedic applications including spinal fusion, fracture fixation, ligament repairs, tendon transfers and lengthenings, osteotomies, joint replacement, trauma, pediatric applications and limb salvage following tumor resection.

TECHNICAL NEEDS

The engineering developments needed to make computer-based pre-operative planning the standard of care in orthopaedics are related to gathering the imaging data, creating models of the musculoskeletal system based on the data and providing an interface which enables the clinician to quickly and easily obtain accurate data. An automated process for constructing musculoskeletal models from imaging data is a research priority to

continued

allow rapid assessment of clinical cases. The key to the musculoskeletal models is allowing independent manipulation of the individual components of the model (bone, soft tissues, prosthetic devices, etc.). Additional work is also needed to develop imaging techniques which can be used to determine the structural properties of the soft and hard tissues included in the models. In addition, the parameters which will be utilized for pre-operative planning need to be identified based on engineering analyses and outcome studies. The methods for biomechanical analysis need to be optimized for speed and accuracy. Additional work is also needed on developing user interfaces for health care providers to utilize the developed applications.

NON-TECHNICAL ISSUES

The non-technical issues are related to costs associated with development of the applications and distribution of the applications to the orthopaedic community. The costs related to the development of the applications are primarily related to research costs. The costs of potential liability related to unexpected outcomes must also be considered. The cost of the added planning time of the surgical team and the added costs of additional imaging procedures must also be considered and is related to deciding which patients require pre-operative planning. Reimbursement for the pre-operative planning is also an important issue. Applications should also be developed to ensure that all the analyses can be utilized by surgeons of varying experience and educational backgrounds. Establishing the trust of the orthopaedic surgeon in the analyses provided and obtaining FDA approval for pre-operative planning applications is another important issue.

RECOMMENDATIONS

Recommendations are focused on incorporating research activities at several institutions into applications which can be utilized by all practicing orthopaedic surgeons to improve patient care. In particular, an emphasis needs to be made on encouraging collaboration between research centers to develop new technologies into deliverable products. The AAOS and/or NIH are viewed as the most appropriate bodies to carry out the recommended actions in order to obtain pre-operative planning tools which can be provided to all clinicians that allow application of devices from a wide variety of manufacturers.

We recommend that the AAOS:

- Educate the orthopaedic community, particularly the residents, on the current and future role of computer technology and medical imaging in orthopaedics.
- Take a leadership role in coordinating pre-operative planning systems. The AAOS could undertake the development of a framework for pre-operative planning applications. Individual components could be submitted to the AAOS for inclusion into the framework from various research centers.
- Help to establish collaborations between research institutions which match expertise to aid rapid development of the pre-operative planning tools.
- Solicit appropriate funding for the development of the applications. The funding could be provided by a combination of government and industrial sources. The AAOS could also define a standard format for imaging data and analysis software to ease distribution of images/analyses to all practicing surgeons.
- Form a standing committee on computer assisted orthopaedic surgery to work with NIH to provide research funding, integrate new educational initiatives into the annual meeting of AAOS, develop standards to enhance development/transfer of computer aided surgery systems, act as advocates to encourage medical care payers to reimburse for pre-operative planning and define needs for future development.

Participants

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APPENDIX I

WORKSHOP PROGRAM

NIH/AAOS Workshop on "New Engineering Technology Transfer in Orthopaedics"
April 30 - May 3, 1998, Sheraton North Hotel, Baltimore, MD

Workshop Director: Ed Chao; Co-Directors: Bill Bargar and Tony DiGioia

Thursday, April 30, 1998

5:00 pm - 8:00 pm	Registration and distribution of handout materials
7:00 pm - 10:00 pm	Dinner meeting for workshop chairs and break-out session leaders

Friday, May 1, 1998

7:00 am - 8:00 am	Registration and continental breakfast
8:00 am - 8:10 am	Welcome and Opening Remarks, Edmund Y. S. Chao, Ph.D.
8:10 am - 8:40 am	Patrick J. Kelly, M.D., New York University: *"Recent Advances in Neurosurgery and Their Outlook for the Next Century"*
8:40 am - 9:10 am	Louis R. Kavoussi, M.D., Johns Hopkins University: *"Tele-mentoring in Urological Surgery"*
9:10 am - 9:40 am	Dwight A. Meglan, Ph.D., Mitsubishi Electric Information Technology Center: *"Virtual Reality Surgical Simulator and its Role in Medical Research and Education"*
9:40 am - 10:10 am	Discussion
10:10 am - 10:30 am	Coffee break
10:30 am - 11:00 am	Richard Robb, Ph.D., The Mayo Clinic and Mayo Foundation: *"Volume Rendering and Anatomy Modeling in Image Guided Surgery"*
11:00 am - 11:30 am	Elliot Fishman, M.D., Johns Hopkins University: *"3D Orthopaedic Imaging in Clinical Practice"*
11:30 am - 11:50 am	Kirby Vosburgh, GE Corporate Research and Development: *"Image Acquisition - Current Systems and Trends Relevant to Orthopaedics"*
11:50 am - 12:30 pm	Discussion
12:30 pm - 1:30 pm	Lunch
1:30 pm - 2:00 pm	Jim Anderson, Ph.D., Johns Hopkins University: *"Telemedicine, Telesurgery and Image Guided Interventions"*
2:00 pm - 2:20 pm	Kenneth Krackow, M.D., The Buffalo General Hospital: *"Current Activities in Computer-Assisted Total Knee Replacement"*
2:20 pm - 2:35 pm	Yoshio Koga, M.D., Kobari Hospital, Niigata, Japan: *"Three Dimensional Leg Alignment Assessment by Computed Radiology"*
2:35 pm - 2:50 pm	Kasuo Kiguchi, Ph.D., Niigata College of Technology: *"New Knee Simulation System Controlled by Fuzzy-Neural Networks"*
2:50 pm - 3:10 pm	Discussion
3:10 pm - 5:30 pm	Break-out sessions
7:00 pm -10:30 pm	Reception and dinner

Saturday, May 2, 1998

7:00 am - 8:00 am	Continental breakfast
8:00 am - 8:30 am	Richard M. Satava, M.D., Yale University: *"Advanced Technologies in Medicine and Surgery in the 21st Century"*
8: 30 pm - 9:00 pm	Edmund Y. S. Chao, Ph.D., Johns Hopkins University: *"Use of Modeling, Simulation and Visualization Techniques for Biomechanical Research, Education and Clinical Applications"*
9: 00 am - 9:30 am	Scott Delp, Ph.D., Northwestern University: *"Pre-operative Planners and Surgical Simulators"*
9:30 am- 10:00 am	Discussion
10:00 am - 10:20 am	Coffee break
10:20 am - 10:50 pm	Anthony M. DiGioia, M.D., Carnegie Mellon University: *"Robotics, Image Guidance and Computer Assisted Orthopaedic Surgery"*

continued

Saturday, May 2, 1998, continued

10:50 am - 11:20 am	William L. Bargar, M.D., Sacramento, CA: *"ROBODOC, Its Development, History, Clinical Relevance and Future Prospects"*
11:20 pm - 12:00 pm	Discussion
12:00 pm - 1:30 pm	Lunch break
1:30 pm - 4:00 pm	Break-out sessions

Sunday, May 3, 1998

8:00 am - 9:00 am	Continental breakfast
9:00 am - 11:00 pm	Presentations of each break-out section (15 minute presentation/ 15 minute discussion for each section)
11:00 am - 11:30 am	Closing Remarks and future plan. Edmund Y. S. Chao, Ph.D., Bill Bargar, M.D., Tony DiGioia, M.D.
11:30 am - 1:30 pm	Working lunch for the co-chairs and session leaders to wrap-up the workshop report.

APPENDIX II: ABSTRACTS

RECENT ADVANCES IN NEUROSURGERY AND THEIR OUTLOOK FOR THE NEXT CENTURY

Patrick J. Kelly, M.D., New York University Medical Center

With the advent of computer based imaging – first CT, then MRI – computers were used to calculate stereotactic coordinates for imaging defined targets. As computers became more powerful, they were used to reformat the imaging data bases so that a surgeon could have some appreciation of surgical anatomy. With the availability of low cost, high speed microprocessor based workstations computers became more powerful and as programming languages and user interfaces became more intuitive, computers have become more pervasive and their applications in neurosurgery have increased in number. It is anticipated that state-of-the-art neurosurgery will become computer-based and employ all or a combination of the following technologies: Frameless Stereotactic Surgery, Robotic Technology, Microrobotic Dexterity Enhancement and Telepresence Robotics. In addition, high speed telecommunications technologies will foster better communications between neurosurgeons and their patients world-wide and accelerate competition between neurosurgical centers which may drive costs down and improve quality.

A MINIMALLY INVASIVE METHOD FOR DETERMINING THE LOCATION OF THE CENTER OF THE FEMORAL HEAD DURING TOTAL KNEE ARTHROPLASTY

Kenneth A. Krackow, M.D., The Buffalo General Hospital

Introduction: Proper alignment at total knee arthroplasty requires determination of the mechanical axis of the lower extremity. This study describes for the first time a procedure to locate accurately the center of the femoral head using clinically practical optical tracking instrumentation. No imaging (X-ray, CT, MRI), no additional surgical exposure, and no invasive pre-operative marker placement are required.

Methods: Eight limbs from fresh, whole cadavers were used. Motion data were collected with the OPTOTRAK infrared motion analysis system ($60K, Northern Digital, Ont, CA), (accuracy 0.1 mm. @ 7.2-19.7 ft). Data were analyzed via custom software. Separate rigid body markers were used at the distal femur, proximal tibia, mounted in the room, and fixed to a digitizing probe. Position data from the femoral rigid body was collected as the femur was manually rotated about the hip for 20 seconds. Fifty points were collected in the room frame and analyzed via a least squares fit to a sphere whose center was taken to be the center of the femoral head. This "best fit" center was then transformed into the femoral reference frame. The "true" location of the center of each femoral head was determined via dissection after trials had been completed. The femoral head was cut in half exposing a visually estimated, central, equatorial plane. The visualized center of this plane was digitized in the femoral reference frame. Best fit measurements were carried out by three observers, repeating the measurement 10 times for each limb. The mean and standard deviations for the 10 trials were calculated. Inter-observer repeatability was investigated in a total of four limbs. In total, the distances between 100 best fit center determinations and seven digitized "true" centers were found.

continued

APPENDIX II

Results: Two-sided, paired T-tests (N=100) were used to establish differences in each coordinate direction. In the X (ant-post) direction, a 2.0 mm average error was the smallest and was statistically different from error in the Y (med-lat) direction of 3.3 mm., and in the Z (prox-dist) direction at 3.1 mm, ($P<0.01$). Errors in the Y and Z directions were not different from one another ($P=0.98$). Standard deviations of repeated measures (N=10) on a single limb by a single investigator were generally less than 3 mm in a single direction. Inter-observer variability was quite small, generally less than 1.0 mm, maximum 3.99 mm in one knee in the Z direction. Including all trials, (N=100), which included one specimen with likely inadequate thawing, the computed center was located an average of 5.5 + 3.5 mm from the true (digitized) location. (5.5 mm corresponds to a maximum angular error of 0.8°). Deviation in the medial lateral direction (equivalent to varus-valgus angulation) was generally within 34 mm corresponding to at least 0.5° accuracy.

Discussion: In developing a system to measure the alignment of the knee during total knee replacement surgery, it is desirable to determine the location of the center of the femoral head. This permits construction of the mechanical axis and determination of joint alignment. The method described here provides the necessary accuracy and precision to meet this goal, without the need for additional procedures or radiographic images. The anticipated translation error from this method results in angular errors of less than 1.0°. Importantly, use of this or similar methods may also be appropriate for future computer assisted or robotic surgical systems.

Conclusion: In a controlled study, extramedullary instrumentation was shown to be more accurate and more reproducible than was IM instrumentation.

SIMULATION-BASED SURGICAL TRAINING

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Flight simulation has been used successfully to train commercial and military pilots for more than 30 years. It is essential since: 1) training in the real aircraft is dangerous to passengers, the public, the pilot and the aircraft, 2) rapid cognitive assessment and proprioceptive action is required, 3) training for emergencies is difficult, and, 4) the aircraft is expensive to operate. Surgery training, especially in minimally invasive procedures, has similar difficulties and yet simulation-based training is only now working its way through research and development to productization. Differences in the business environments and technical challenges between the two types of simulation have slowed the emergence of surgical trainers. Advances in cost effective computational technology as well as mathematical modeling and numerical techniques are allowing such trainers to be financially feasible. Not all surgical training requires a simulation trainer just as not all aspects of flight instruction use simulation. Careful evaluation of surgical procedures and subtasks within those procedures is needed to select those aspects which will benefit. Such criteria, while objective to some degree, still embody a great deal of subjectivity. Once activities have been chosen, techniques learned from the evolution of flight trainers are applied to the human factors and training elements to define what is essential to the learning experience. This information is currently being combined with multi-disciplinary engineering and software engineering practices to create commercial quality simulation-based surgical trainers. Ascertaining the utility of these trainers in enhancing the outcomes of minimally invasive surgical medicine will be the essential next step.

VOLUME RENDERING AND ANATOMY MODELING IN IMAGE GUIDED SURGERY

Richard A. Robb, Ph.D., The Mayo Clinic and The Mayo Foundation

Interactive visualization, manipulation and measurement of multi-modality 3D images on standard computer workstations has been developed, used and evaluated in a variety of biomedical applications for more than a decade. These capabilities have provided scientists, physicians and surgeons with powerful and flexible computational support for basic biological studies and for medical diagnosis and treatment. Our own comprehensive software systems, ANALYZE™ and VRASP, have been applied to a variety of biological, medical and surgical problems and used on significant numbers of patients at many institutions. This scope of clinical experience has fostered continual refinement of approaches and techniques, especially 3D volume image segmentation, classification, registration and rendering, and has provided useful information and insights elated to the practical clinical usefulness of computer aided procedures and their impact on medical treatment outcome and cost. This experience has led to design of an advanced approach to computer aided surgery (CAS) using Virtual Reality (VR) technology. VR offers the promise of highly interactive, natural control of the visualization process,

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provide realistic simulations of surgery for training, planning and rehearsal. We have developed efficient methods for the production of accurate models of anatomic structures computed from patient-specific volumetric image data (such as CT or MRI). These models can be enhanced with textures mapped from photographic samples of the actual anatomy, and when used on a VR system, such models provide realistic and interactive capabilities for surgical training, surgery planning and procedure rehearsal on specific patient data. VR technology can also be developed in the operating room to provide the surgeon with on-line, intra-operative access to all pre-operative planning data and models can be fused with real-time data in the OR to provide enhanced reality visualizations during the actual surgical procedures.

Virtual Endoscopy (VE) is a new method of diagnosis using computer processing of 3D image datasets (such as CT or MRI scans) to provide simulated visualizations of patient specific organs similar or equivalent to those produced by standard endoscopic procedures. Conventional endoscopy is invasive and often uncomfortable for patients. It sometimes has serious side effects such as perforation, infection and hemorrhage. VE visualization avoids these risks and can minimize difficulties and decrease morbidity when used before actual endoscopic procedure. In addition, there are many body regions not compatible with real endoscopy that can be explored with VE. Eventually, VE may replace many forms of real endoscopy. Other applications of virtual reality technology in medicine which we are developing include anesthesiology training, virtual histology and virtual biology, all of which provide faithful virtual simulations for training, planning, rehearsing, and/or analyzing using medical and/or biological image data.

There remains a critical need to refine and validate CAS and VR visualizations and simulated procedures before they are acceptable for routine clinical use. We have used the Visible Human Dataset from the National Library of Medicine to develop and test these procedures and to evaluate their use in a variety of clinical applications. We have developed specific clinical protocols to evaluate virtual surgery against surgical outcomes and to compare virtual endoscopy with real endoscopy. We are developing informative and dynamic on-screen navigation guides to help the surgeon or physician interactively determine body orientation and precise anatomical localization while performing the virtual procedures. Additionally, the adjunctive value of full 3D imaging (e.g., looking "outside" the normal field of view) during the virtual surgical procedure or endoscopic exam is being evaluated. Quantitative analyses of local geometric and densitometric properties obtained from the virtual procedure ("virtual biopsy") are being developed and compared with other direct measures. Preliminary results suggest that these virtual procedures can provide accurate, reproducible, and clinically useful visualizations and measurements. These studies will help drive improvements in and lend credibility to virtual procedures and simulations as routine clinical tools. CAS and virtual reality assisted diagnostic and treatment systems hold significant promise for optimizing many medical procedures, minimizing patient risk and morbidity, and reducing health care costs.

3D ORTHOPAEDIC IMAGING IN CLINICAL PRACTICE

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Over the past two decades the radiologic armamentarium for the evaluation of orthopaedic pathology has evolved from plain radiographs and linear tomography to Spiral CT scanning and MR imaging. CT has always played a major role in orthopaedic imaging for a wide range of applications including trauma, infection, oncology and congenital diseases. With the advent of Spiral CT there has been an increased interest in CT applications in great part to the advantages of the spiral CT acquisition technique which results in the ability to acquire true volume data sets in a 25-40 second time frame and reconstruct that data at any arbitrary increment Developing in nearly a parallel path has been computer based imaging which has benefited from ever faster workstations (with better cost/performance ratios) and more sophisticated graphics software (especially algorithms). By taking advantage of these developments we have been able to design 3D software programs that run on lower cost platforms while developing capabilities never before possible. Rather than being just an adjunct study this newer capabilities promise to drive 3D orthopaedic imaging into a more mainstream pathway.

The conventional technique for the generation of 3D images was the use of shaded surface displays using binary classification techniques. Due to the well known limitations of this technology, including poor image quality, pseudolesions due to incorrect thresholds, and often complicated image editing, the techniques have never led to wide usage in the radiologic community. The newer algorithms are volume rendering techniques which use a

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percentage classification method for generating images. The technique as implemented on a SGI Infinite Reality or 02 workstation is done in real-time without the need for any pre-rendering editing or processing. The images are interacted by the user within real-time and with the use of various parameter settings including opacity highly accurate to the initial data set. The images can be reviewed on the workstation as either a real time display or with a stereoscopic display. We find that stereo viewing is especially helpful in areas of complicated anatomy.

In this session we will review some of the basic principles of 3D CT imaging with a focus on clinical applications. Specific topics addressed include study technique and design as well as the various reconstruction algorithms available. We will then address the clinical role of 3D imaging from a perspective of what is commonly done today and in what directions we can expect innovation to travel. The typical applications that will be addressed include trauma imaging, oncologic imaging and inflammatory disease. The use of specific programs that help with metal reduction artifacts in post operative patients will also be addressed. Finally the developing role of real time CT and its potential impact in the acute care setting will be discussed.

IMAGE GUIDED INTERVENTIONS

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Recent technological advances in imaging and engineering and concerns for reducing health care costs have stimulated considerable interest in both the medical and pubic sectors in the use of image guided therapeutic techniques to minimize the invasiveness and reduce the costs of many surgical and therapeutic procedures. The common thread linking all image guided procedures is the need to visualize the area of treatment and monitor its progress. Significant improvements in computer assisted image acquisition, processing and presentation have provided new opportunities to expand the traditional diagnostic role of Radiology to include therapy. Medical imaging modalities such as conventional X-ray, CT, ultrasound and Magnetic Resonance Imaging (MRI) enhance the opportunity to guide and percutaneously or transcutaneously deliver therapy with precise accuracy and in a manner that is less invasive than laparoscopic surgery. Important research topics in image guided therapy include:

a. registration of real-time medical images with preoperative 3D renderings.
b. tissue segmentation and multiple image registration techniques.
c. instrument tracking and sensing in real-time imaging modalities.
d. 3D image preoperative planning.
e. physical and anatomical modeling for therapeutic simulations.
f. soft tissue and frameless stereotactic localization systems.
g. development of intraoperative robotic/manipulation systems.
h. development of novel therapeutic end effectors.
i. teleinterventions using remote sources of guidance.
j. development of augmented or hybrid reality display systems.
k. development of image guided-robotic integration systems.

Our work involves developing a broadly applicable image guided surgical augmentation system that registers real-time imaging with preoperative 3D reconstructed images of lesions and directs a remote center-of-motion robotic manipulator to quickly and accurately target the lesion and percutaneously deliver a pre-planned pattern of localized therapy. The advantages of using an image guided robot include rapid accurate targeting of multiple areas within the lesion and compensation for patient motion. Our robotic manipulator consists of a 3-axis linear translation stage, a 2-axis parallel four bar linkage providing two rotations about a "fulcrum" or remote motion center point and a 2-axis distal component providing instrument insertion and rotation motions passing through the remote motion center. A complex geometric task specification (implant shape and placement, therapy pattern and approach paths) is developed from preoperative CT images. Implanted fiducial markers are used to register the preoperative CT coordinate system with the intraoperative robot coordinate system, and a robotic device is used for precise execution. Our preliminary work with this system has focused on phantoms and initial animal experimentation. Preliminary results and applications will be presented.

APPENDIX II

TELESURGICAL CONSULTATION: ATTEMPTING TO IMPROVE THE STANDARD OF CARE

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Introduction and Objectives: Laparoscopy has demonstrated economic, individual and social benefits. Unfortunately, laparoscopy is associated with steep learning curves, and the incidence of complications has clearly been shown to be inversely related to experience. The initial high complication rate and lack of adequately trained endoscopic surgeons have raised concerns over training, granting of hospital privileges, and most important, patient safety. Our goal was to develop a telesurgical system which would allow an endoscopic specialist at a remote site to offer guidance and assistance to a laparoscopic surgeon.

Methods: A system was designed and developed which connected a remote site and an operative site, a distance of approximately 3.5 miles, via a single T1 (1.54 Mb/sec) communications link. The system provided real-time video display from either the laparoscope or an externally mounted camera, duplex audio, telestration, control of a robotic arm which manipulated the laparoscope, and the ability to activate electrocautery device.

Results: Seven patients underwent laparoscopic procedures using this telesurgical system. In all cases, the primary surgeon was less experienced in the laparoscopic approach but had basic skills to obtain intraperitoneal access. All seven cases were successfully completed without complication.

Conclusions: We have developed a practical and affordable telesurgical system which allows assessment of a surgeon's performance and intervention by a remote specialist submerged in the operative site's environment. These initial studies have demonstrated the feasibility and effectiveness of telesurgical consultation. Telesurgical consultation can greatly impact surgical education, credentialing and patient care by offering to patients and their surgeons global access to surgical specialists.

THREE DIMENSIONAL LEG ALIGNMENT ASSESSMENT BY COMPUTED RADIOLOGY

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Objectives: Several image techniques such as CT have been applied for detection of position during robot assisted surgery; however, a plain X-ray is the most practical technique in orthopaedic clinics. We propose the anatomical coordinates system which is used for three dimensional leg alignment assessment directed by standing biplanar (AP and 60° oblique) CR (computed radiography, Fuji Film Company).

Assessment System: A special long cassette holder with metal ball markers to estimate direction and position of X-ray projection is used. Biplanar X-ray information is transferred directly to a personal computer. After establishment of a three dimensional space of X-ray films by the digitizing markers, several anatomical landmarks are digitized to define the coordinates system. For the femoral coordinates system, posterior parts of the medial and lateral condyles are detected as a circle. The connecting line of these centers is defined as the X-axis and the mid-point as the origin. The line from the origin to the center of the femoral head is defined on the plane of Z-, X-axis. The tibial origin is defined as the center of the proximal tibial joint surface, and the connecting line of the center of the proximal and distal joint surfaces is defined as the direction of X-axis. These coordinate systems can be reconstructed in routine right angle biplanar X-ray by a fitting technique: for femoral coordinates, the mid-line of the femoral shaft and the most prominent point of the metaphysis, and for tibial coordinates, the mid-line of the tibial and the fibular shafts and the apex of the fibular head are used.

Accuracy: The position error of this digitizing methods is less than 2 mm for the detection of origin and within 1.5° for the direction of the coordinates system. These margins of error are improved by introducing the information from the CT image.

Conclusions: This coordinates system can be used, not only in the assessment of three dimensional leg alignment but also in the detection of three dimensional position relation during robot assisted surgery.

APPENDIX II

NEW KNEE SIMULATION SYSTEM CONTROLLED BY FUZZY-NEURAL NETWORKS

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Several kinds of knee motion simulator systems have been developed for the accurate analysis of knee biomechanics. The knee motion simulators, however, are not recognized for the practical use because of difficulty in control of kinematics and mechanics (which is mainly based on the strength of muscle and body weight). We developed a new knee simulation system, which controls the 3D positional relation of tibia and femur, to generate the physiological knee motion. Many clinical studies have been performed to analyze the length displacement pattern of the Anterior Cruciate Ligament (ACL) and the Posterior Cruciate Ligament (PCL). Monitoring the length displacement patterns of two different bundles of each ACL and PCL, physiological 3D positional relation of knee flexion can be demonstrated using DC motors. The experimental data of the length displacement pattern is obtained from the literature. A goniometer is used to measure the flexion angle of the knee.

There is difficulty in controlling the knee motion with a conventional control policy since it is difficult to make a precise mathematical knee joint model which is required for the conventional controller. Therefore, a fuzzy neural control policy, one of the most effective intelligent control policies, has been applied to the controller of the knee motion simulator in this study. Applying the fuzzy neural control policy, human knowledge and experience can be reflected in the control policy and adaptive/learning ability can be incorporated in the controller. Learning the fuzzy neural controller is carried out to minimize the evaluation function. Consequently, the desired motion can be realized using the squared error between the desired displacement patterns and the current displacement patterns as the evaluation function.

ADVANCED TECHNOLOGIES IN MEDICINE AND SURGERY IN THE 21ST CENTURY

by Richard Satava, M.D., Yale University, Department of Surgery

Minimally invasive surgery is stabilizing in its clinical application, and other competing technologies are beginning to emerge. Arthroscopy, which was once considered a major change in surgery, may actually have been a transition in the pathway to even more minimally invasive and even non-invasive surgical procedures.

Newer technologies of robotics, telepresence surgery, remote manipulation and dexterity enhanced surgery may also be on the pathway to wherever the future is taking us. In addition the other components of surgery, such as pre-operative planning, intraoperative navigation and surgical education and training must not only evolve along with the technical components of the operative procedures but also integrate the entire spectrum of health care.

In order to keep pace with the transition, it is essential to understand the fundamental concept involved in thinking in Information Age terms, rather than the traditional Industrial Age mindset. This enables entirely new capabilities in the new generation of medicine, which also includes the infrastructure of telemedicine, medical informatics, high performance computing, 3D visualization and point of service health care with ubiquitous real-time access through telecommunications. These applications are mediated through the computer and information networks and as such are the essence of the paradigm shift in the field of medicine

This infrastructure supports a number of enabling technologies which will usher in and support the next generation of medical interventions. These include real-time image acquisition, point of care data acquisition, 3D visualization, computer enhancement (through digital signal processing, scaling, filtering, etc.), remote manipulation and telepresence, and distributed networking. In order to move beyond minimally invasive procedures and completely benefit from the computer aided revolution, we must take the broadest interpretation and a strategic global view where the integration of technologies results in capabilities beyond those of the individual devices; however, we must balance the technology with human compassion and empathy and with these technologies can provide an enhanced quality of medical care for each and every patient.

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USE OF MODELING, SIMULATION AND VISUALIZATION TECHNIQUES FOR BIOMECHANICAL RESEARCH, EDUCATION AND CLINICAL APPLICATIONS

Edmund Y. S. Chao, Ph.D., Orthopaedic Biomechanics Laboratory, Johns Hopkins University

Introduction: Using virtual reality simulation techniques in orthopaedic research is still in a rudimentary stage. The advantage of such techniques lies in their ability to provide realistic models for anatomical structures to predict the treatment outcome of joint replacement, skeletal fracture fixation, soft tissue injury and repair under simulated loading conditions. After incorporating the physical and material properties, the models can be used to conduct experimental tests on computer workstations with unlimited parametric variations to study the musculoskeletal joint system involved in orthopaedic surgery and biomechanical research. Since these models are quantitative and interactive, they can predict and animate the performance of treatment alternatives as a means of pre-operative planning. The aim of this presentation is to introduce the virtual biomechanical model of human musculoskeletal system and to illustrate its practical applications. It is hoped that this technology and the associated database and model will be widely utilized in the orthopaedic research community worldwide. With the disadvantages and limitations involved in using human cadaver specimens for testing, this new technology can have a significant impact on the quality and reliability of biomechanical investigations for the future.

Virtual model development: Whole cadaver or specific anatomic parts with no previous history of orthopaedic trauma were placed in neutral or functional positions for MRI scan. T1 weighted images of 3 mm thickness with 256x256 resolution were taken from head to toe. The specimens were then frozen in the same position and scanned by a GE CT/T 9800 to collect transverse plane images at 1.5 mm thickness with 512x512 resolution. A high speed band saw was used to serially section the cadaver at corresponding intervals for monochrome (1024x753) and color (756x486) digital images. Calibration frames were used to correct lens distortion. Using thresholding techniques to isolate individual structures, parametric surface representations based on three dimensional meshes were stored as nodal and connectivity arrays. The lack of contrast in soft tissue structures in the scan data was supplemented by the cryo-sectional video images. The resulting geometric models were adapted to the Visual Interactive Multibody Simulation Software (VIMS) which solves the dynamic equations of motion using measured kinematic data (from cadaver or instrumented mannequins), external impact forces, tissue and organ material properties, and the vehicle boundary conditions following the **"Inverse Dynamic Problem"** solution algorithm. Muscle and joint constraining forces are determined by optimal programming techniques. Joint contact pressure and the state of stress/strain in bone are analyzed using a variety of numerical methods such as the Finite Element Analysis (**FEA**) and the Discrete Element Analysis (**DEA**).

Results and application: To validate the geometric model, both rendered volumes and anatomical landmarks are measured and compared with the visual image data. The landmark measurement chosen is the distance between the trochanter and lateral epicondyle. Intersegmental forces at the knee and hip are determined during various exercises to study the effect of muscle co-contraction. Shoulder kinematics were analyzed for the complex composite movement, impingement syndromes and the change of costoclavicular triangle area (Thoracic Outlet Area). Such analysis and visual display of the vital biomechanical data serve the basis for computer-aided preoperative planning and rehabilitation scheme optimization to assure the efficacy and safety of the treatment in patients being considered for joint replacement, bone fracture management, ligamentous injury repair, limb lengthening and angular alignment, etc. The skeletal structure relative positions can be altered interactively to simulate body posture involved during different functional activities and abnormal joint functions. In addition, stress occurred at the joint articulating surfaces and ligamentous tension can be calculated under both static and dynamic loading conditions. Actual dynamic activities of test subjects can be incorporated to the model for force and joint stress analyses using a non-linear mapping algorithm based on established bony landmarks from radiograms or CT scan data. Coupled movement at the shoulder, joint alignment surgery (osteotomy), normal and abnormal joint contact stresses, joint and muscle forces during gait and sports activities are used as the examples to illustrate the enormous utility of this new simulation technology in medical research, education and health care.

Discussion: This unique simulation technique can be described as the Virtual, Interactive, Computational, Anatomical Model (**VICAM**) for biomechanical analysis of the musculoskeletal system under static or dynamic

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loading conditions and in normal, abnormal and surgically altered states while allowing results to be visualized graphically with the model. Memory saving features allows graphical animation of system function on computer workstations as a powerful tool for research and patient care in orthopaedic surgery and rehabilitation. Validity of such application depends upon model verification using anatomic specimens loaded on **Dynamic Joint Simulator**. This unique technology will create unlimited opportunities to reliably examine orthopaedic implant design, the efficacy of protective device and vehicle safety features, disease progression secondary to trauma, pre-treatment planning and clinical outcome through simulation in shorter time-span and at substantially reduced cost. Such a model may also be used to generate the Virtual Human models and the surgical simulator to facilitate medical personnel training and lay public education.

COMPUTER-ASSISTED SURGERY: FROM MUSCULOSKELETAL MODELING TO IMAGE-GUIDED SURGERY

Scott L. Delp, Ph.D., Northwestern University

The outcomes of surgeries performed to improve musculoskeletal function are sometimes unpredictable. This problem exists, in part, because the development and testing of new operative techniques rely almost entirely on clinical trials (i.e., trying surgeries on patients) in which the means to quantify surgical changes or predict post-operative results do not exist. I believe that the design and analysis of operative procedures can proceed more effectively if musculoskeletal models are developed that explain and predict the functional consequences of surgical interventions. We have developed computer graphics models to simulate the biomechanical consequences of bone reconstructions, muscle-tendon surgeries, and joint replacements. We have also developed a system that can be used in the operating room to implement individualized surgical plans. This presentation will review the results of our computer-assisted surgery systems that have been used to design and implement surgical procedures used in the management of cerebral palsy and osteoarthritis.

IMAGE GUIDED SURGICAL NAVIGATION AND ROBOTIC ASSISTANCE FOR ORTHOPAEDIC SURGERY

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Technologies are emerging which will influence the way we plan, simulate and execute orthopaedic surgery. Recent advances in the fields of medical imaging, computer vision, and robotics have provided the enabling technologies to permit computer aided surgery to become an established area which can address clinical needs. Although these technologies have been applied in industry for over 20 years, the field of Computer Assisted Orthopaedic Surgery (CAOS) is still in its infancy. Image guided and surgical navigation systems, robotic assistive devices and surgical simulators have begun to emerge from the laboratory and hold the potential to improve current surgical practice and patients' outcomes.

The goals of these new clinically focused technologies are to develop interactive, patient-specific preoperative planners to optimize the performance of surgery and the postoperative biologic response, and develop more precise and less invasive "smart" tools and sensors to assist in the accurate and precise performance of surgery. The medical community is beginning to see the benefit of these enabling technologies which can be realized only through the collaboration and combined expertise of engineers, roboticists, computer scientists and surgeons.

An Improved Approach: Image Guided and Surgical Navigation Systems

The use of image guided surgical navigation systems and robotic assistive devices for surgical practice extends beyond just the new computer hardware and software. A primary goal of these new enabling technologies is to couple and tightly integrate preoperative planning with intraoperative execution. Using this improved approach, we will be able to simulate and optimize a preoperative plan as well as to assist surgeons by integrating sophisticated preoperative medical images directly into the operating room. Most importantly, these enabling technologies will provide a new generation of measurement devices and sensors never before available which can provide intraoperative information to surgeons on line during the actual procedure. Providing this information in a timely manner will permit surgeons to gauge their current practice, then use their judgment and act on the

continued

information all during the actual surgery. These enabling technologies will provide surgeons with precise imaging and planning information that are routinely used in practice (CT or MRI data) as well as the positions and locations of surgical tools and bone anatomy during the actual surgery.

As an extension of this new approach, a new generation of preoperative planners will permit surgeons not only to plan geometrically (i.e., size and orientation of implants) but also to optimize the intervention based on individual patient specific information (i.e., bone anatomy or simulations of range of motion). Once the optimal plan is developed, surgeons will be able to accurately and precisely implement that plan. Only by coupling preoperative medical images and optimized plans with accurate tools used during surgery, will the full potential of these new enabling technologies be realized.

The new technologies will also provide clinical researchers with a new generation of measurement devices and intraoperative sensors which will permit the quantification of current clinical practice and provide information about surgical procedures and techniques never before available during surgery. Such quantification of intraoperative variables can then be used to more precisely analyze and validate long-term clinical outcomes.

The overall goal of these technologies is not to replace surgeons but to assist them in performing tasks. The aim is to couple the abilities of surgeons with these computer assisted devices and potentially accomplish surgical tasks that neither could ever accomplish individually. For the first time, we will also be able to quantify and improve current surgical practice by developing complete, clinically useful, image guided surgical navigation technologies and robotic assistive tools.

ROBODOC

Its Development, History, Clinical Relevance and Future Prospects

William Lamont Bargar, M.D., Sacramento, CA

The ROBODOC project has evolved in five phases over an eleven year period:

Phase I: (1986-87) was a laboratory feasibility study conducted at the IBM Thomas Watson Research center in Yorktown Heights, New York to determine if it was possible to program a robot to perform a complex milling task that was unique for each patient. A new computer language developed by IBM made it possible.

Phase II (1987-89) was a two year study at the University of California (UC), Davis funded by a grant from IBM to develop the system in the laboratory. Major hurdles in image processing and registration were overcome and studies showed that the robotically machined femurs were prepared with improved accuracy of up to two orders of magnitude.

Phase III: (1989-91) was another two year study at UC, Davis and the Sacramento Animal Medical Group to bring the system into a surgical environment. Twenty six canine total hip replacements were performed on clinical dogs with hip dysplasia. The system was shown to be feasible and all 26 dogs recovered well and appeared to have less pain and better function than dogs operated on with conventional means.

Phase IV: (1992-93) was performed at the request of the FDA. Initially, on the basis of our canine experience, we requested authorization to perform a large multi-center study on humans. The FDA felt that a human feasibility study should be done using only ten patients. These were all performed successfully and the results were reported at the 1994 AAOS meeting. The conclusions were that the procedure appeared to be safe and that feasibility was established but the number of patients was too small to determine efficacy.

Phase V (1994-present) consists of an FDA authorized multicenter study with concurrent controls using three sites in the United States and a prospective ongoing post-market study at one site in Germany. The results of the FDA study show no difference in clinical parameters at two years but radiographic parameters show superiority of fit, position and radiolucencies for the Robodoc group. The German experience to date is with over 1300 cases at nine centers. No fractures or robot related major complications have occurred. Significant improvements have been made in operating time and efficiency. Thirty revision hip replacements have been performed allowing simultaneous cement removal and femoral bone preparations for the new implant. Future prospects for Robodoc include pinless registration, revision total hip replacement and total knee replacement.

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